

Applicant : Kent Harrison  
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### REMARKS

In the Action mailed June 9, 2005, the Examiner rejected all non-withdrawn, pending claims 1-4, 7-18, 23, 24, 35, 36, 38-41 and 43. Claims 5, 6, 19-22 and 37 had previously been withdrawn from consideration, and claim 42 was withdrawn in the present Action. In response, Applicant has amended claims 1, 35 and 40. As such, claims 1-24 and 35-43 are pending, although of those, claims 5, 6, 19-22, 37 and 42 are presently withdrawn from consideration.

In view of the amendments to the claims and the following remarks, Applicant requests reconsideration of the patentability of the rejected claims 1-4, 7-18, 23, 24, 35, 36, 38-41 and 43; and asks that the Examiner consider, pursuant to 37 CFR 1.141, the patentability of withdrawn claims 5, 6, 19-22, 37 and 42 as being in dependent form and including all the limitations of an allowed generic claim.

#### **Claim Rejections – 35 USC §§ 102 and 103**

The Examiner rejected claims 1, 7-9, 35, 38, 39, 40 and 43 (of which, claims 1, 35 and 40 are independent) under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6, 575,966 to Lane et al. In particular, the Examiner contended that Lane et al. disclose an elongated catheter device for endovascular insertion with a balloon at the distal end for directly cooling tissue. The Examiner deemed the balloon to be the claimed deployable structure, in that the Examiner stated: "The balloon is inflated (deployed) using cooling medium to contact the tissue to be treated."

The Examiner rejected all other remaining non-withdrawn, pending claims 2-4, 10-18, 23, 36 and 41 (of which, claim 10 is independent) under 35 U.S.C. 103(a) as being unpatentable over Lane et al. in view of U.S. Patent 5,799,661 to Boyd et al. Although the Examiner conceded that Lane et al. do not teach a deployable cooling structure with a pad like structure and a sheath longitudinally over the deployable structure, the Examiner stated that Boyd et al. teach a device for cooling tissue comprising an elongate shaft (Fig. 42, # 233) with a deployable cooling structure at its distal end (Fig. 42, # 239). The Examiner contended it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the deployable cooling structure as taught by Boyd et al. in place of the deployable balloon of Lane

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et al. as an alternative equivalent deployable cooling means. The Examiner further contended that the cooling of body tissue not easily accessible is common to both inventions, making it obvious to look to other inventions that teach delivery of cooling means to such inaccessible areas.

For the reasons discussed below, Applicant disagrees with the Examiner, and submits that each of the independent claims 1, 10, 35 and 40 define an invention that is patentable over the prior art, as do their respective dependent claims. Applicant's distinguishing the Lane et al. reference from Applicant's claims should not be taken as an admission that Lane et al. is properly considered prior art under any sub-section of 35 U.S.C. 102.

Lane et al. discloses an elongated catheter device with a distal balloon assembly that is adapted for endovascular insertion. (Abstract.) Lane et al. further discloses that coolant injected through the device may, in different embodiments, directly cool tissue contacting the balloon. (Abstract.)

Boyd et al. discloses devices and methods for performing port-access or closed-chest coronary artery bypass surgery, including a topical hypothermia device for use during a port-access bypass procedure. The topical hypothermia device has a flexible heat exchanger that is collapsible into a pre-deployable position to fit through an access port into the chest of a patient. The topical hypothermia device also includes a tubular shaft made of a rigid material, such as stainless steel or a rigid plastic. Once inserted into a patient through a chest access port, the flexible heat exchanger is deployed from the topical hypothermia device and placed under the heart for cooling.

Independent claims 1, 35 and 40, and their dependents

Applicants have amended independent claims 1, 35 and 40 to recite that the device's deployable structure is longitudinally deployable from a distal end of the device's elongate body. Support for the amendment appears in Applicant's specification as originally filed, for example, Figures 1-4 and accompanying text. As such, the amendments add no new matter.

As amended, independent claim 1 is directed to a medical device comprising an elongate body having a distal end for entry into a body vessel and positionable near a target tissue region

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within the body. The medical device further comprises a structure longitudinally deployable from the distal end of the elongate body to cool the target tissue region. Independent claims 35 and 40, as amended, are each directed to a method that, in part, uses a catheter having a structure that is longitudinally deployable from a distal end of an elongate body of the catheter.

Lane et al. does not anticipate any of independent claims 1, 35 and 40, as amended. In particular, Lane et al. does not disclose or suggest a device (or a method using a device) that has a structure that is longitudinally deployable from a distal end of an elongate body of the device, as each of claims 1, 35 and 40 require. To the contrary, the Lane et al. device's balloon, which the Examiner deemed to be the claimed deployable structure, is expandable radially at a distal portion of the catheter. Whether or not the balloon in the Lane et al. device can be considered to be deployable, the balloon in the Lane et al. device is not deployable longitudinally from a distal end of an elongate body, as each of claims 1, 35 and 40 require.

Nor does the Lane et al. reference, either alone or in a proper combination with other reference or references, render either claim 1, 35 or 40 obvious. In particular, the device of claim 1 (and the catheter used in the methods of claims 35 and 40) is a new structure that is optimally suited for an important new application of cooling tissue within a heart chamber when blood flow to the heart chamber is temporarily reduced or entirely blocked (so as to reduce reperfusion injury after normal blood flow resumes), which is an application that is not even contemplated by Lane et al. or any other prior art reference at issue. For example, as described in Applicant's specification at page 10, line 19, through page 12, line 25, Applicant's device has an elongate body with a distal end suitable for entry into a body vessel and that may be directed through the body vessel and positioned, for example, within a heart chamber. Once positioned, the deployable structure may be longitudinally deployed from a distal end of the elongate body to cool a target tissue region within the heart chamber. As such, the claimed device, as well as methods using the device, permit the targeted cooling, by direct contact, of tissue located inside a heart chamber.

By contrast, the balloon in the Lane et al. device is described as being used for freezing or cooling tissue on the inner surface of a cylindrical vessel, such as an artery. While perhaps

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theoretically possible to use the balloon catheter device of Lane et al. for cooling tissue within a heart chamber, Applicant's claimed is better than the Lane et al. design for such an application for at least two reasons. First, by having a structure that is deployable longitudinally from a distal end of an elongate body as with Applicant's design, as opposed to expanding radially from a distal portion of an elongate body, Applicant's design provides for a better contact between the device's cooling structure and the tissue that needs to be cooled, as is described in Applicant's specification at page 11, line 25, through page 12, line 12. In addition, using a balloon surface to provide cryotherapy, as with the Lane et al. device, requires sufficiently high pressure to cause the balloon to expand radially so that the outer balloon surfaces contact the inner surface of the cylindrical vessel, whereas with Applicant's device, cooled fluid at a lower pressure may simply be routed through the deployed structure. As such, the potential of a balloon bursting under the pressure of the cryogenic fluid, which also acts to expand the balloon, is not present with Applicant's device.

Furthermore, neither Boyd et al. nor any other reference provides a suggestion to modify the Lane et al. device to provide it with a cooling structure that is longitudinally deployable from a distal end of an elongate body. Importantly, Boyd et al. does not suggest the important new application of cooling tissue within a heart chamber when blood flow to the heart chamber is temporarily reduced or entirely blocked (so as to reduce reperfusion injury after normal blood flow resumes), which again is an application for which Applicant's device is particularly well suited. By contrast, the heat exchanger of the hypothermia device disclosed in Boyd et al. is intended for topical cooling of the entire tissue region on the underside of the heart (i.e., the outside surface of the heart), and is too large to be deployed inside the body. As such, only with the benefit of hindsight could it be said it would be obvious to combine two different references (namely, Lane et al. and Boyd et al.) to render obvious Applicant's claimed device (or method using the device), when, indeed, neither reference contemplates the particular application for which Applicant's device is well suited.

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Accordingly, Applicant requests that the Examiner remove his rejection of independent claims 1, 35 and 40, as well as his rejection of the respective rejected dependent claims 2-4, 7-9, 36, 38-39, 41 and 43.

Independent claim 10 and its dependents

Applicant submits that the combined teachings of Lane et al. and Boyd et al. do not render Applicant's claim 10 obvious, as the Examiner contends. In particular, neither Lane et al., Boyd et al., nor any other reference, suggests modifying the Lane et al. device as the Examiner suggested to provide it with a patch that is deployable from a distal end of an elongate shaft to cool a target tissue region, as claim 10 requires. For reasons similar to those described previously in connection with claims 1, 35 and 40, only with the benefit of hindsight could it be said it would be obvious to combine two different references (namely, Lane et al. and Boyd et al.) to render obvious Applicant's claimed device, when, indeed, neither reference contemplates the particular application for which Applicant's device is well suited.

Accordingly, Applicant requests that the Examiner remove his rejection of independent claim 10, as well as his rejection of the respective rejected dependent claims 11-18 and 23.

Consideration of non-elected dependent claims

Pursuant to 37 CFR 1.142(b), the examiner withdrew claims 5-6, 19-22, 37 and 42 from consideration as being drawn to a non-elected invention. Claims 5-6 depend from claim 1, claims 19-22 depend either directly or indirectly from claim 10, claim 37 depends from claim 35, and claim 42 depends from claim 40. Because independent claims 1, 10, 35 and 40 are each generic and allowable, and the claims that depend from these generic claims include all of the limitation of the generic claims, Applicant contends that dependent claims 5-6, 19-22, 37 and 42 are entitled to consideration and allowance pursuant to 37 CFR 1.141. As such Applicants ask that the Examiner consider these claims.

CONCLUSION

Applicant submits that all pending claims 1-24 and 35-43 are in condition for allowance and respectfully requests that the examiner issue a notice of allowance.

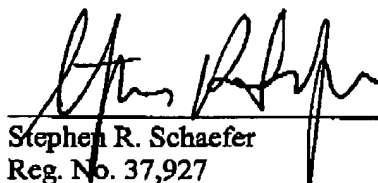
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It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment.

Please charge Deposit Account No. 06-1050 in the amount of \$120 for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: Sep 12, 2005  
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